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EXAMINER	
CLARK, SARA E	

ART UNIT	PAPER NUMBER
4121	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,246	HOLLANDER, ERIC	
	Examiner	Art Unit	
	SARA E. CLARK	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,11-19,21,23-28 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9,11-19,21,23-28 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/10/2006 and 4/26/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

NON-FINAL REJECTION

This application is a 35 U.S.C. 371 (national stage) application of PCT/US03/31493, filed 10/3/2003, which claims benefit of priority to provisional application 60/415,837, filed 10/3/2002. Claims 1, 2, 4-9, 11-19, 21. 23-28, and 30, as amended, are pending.

Election/Restrictions

1. Applicant's election with traverse of Group 2 in the reply filed on 2/5/2009 is acknowledged. The traversal is on the ground(s) that the behaviors listed in all five groups are all characteristics associated with autism. This is not found persuasive because these behavioral characteristics can also have different etiologies with causes entirely distinct from autism. The requirement is still deemed proper and is therefore made FINAL. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/5/2009.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. A proper claim was made in the first line of the specification, and a review of provisional application 60/415,837 shows that the disclosure therein supports the claims of the instant application. Thus, claims 1, 2, 4-9, 11-19, 21. 23-28, and 30 are entitled to an effective filing date of 10/3/2002.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 5/10/2006 and the information disclosure statement (IDS) submitted on 4/26/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the two information disclosure statements have been considered by the examiner.

Claim Objections

4. Claims 5 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

5. The claim or claims must commence on a separate sheet or electronic page (37 CFR 1.52(b)(3)). Appropriate correction is required.

Claim Rejections - 35 USC § 112 First Paragraph

Written Description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 4-9, 11-19, 21. 23-28, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. The specification fails to describe a limiting definition of "oxytocin analog" such that the term as recited in the claims has no clear boundaries.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter as of the filing date of the application. As recognized in the MPEP:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 recognizes that, for a generic claim, the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. Although MPEP § 2163 does not define what constitutes a sufficient number of representative species, the courts have determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The specification defines “oxytocin analogs” as compounds having bioactivity *less than*, similar to, or greater than oxytocin (p. 9, lines 9-10 and p. 11, lines 7-8). By this definition, anything can be an oxytocin analog, such as water; indeed, every compound known to mankind can be classified into one of these three groups. A more limited definition is found on page 6 (lines 10-12) and on page 11 (lines 10-14) which defines oxytocin analogs as compounds, moieties, and/or fragments having bioactivity only similar to or greater than oxytocin. However, this is still very broad and non-limiting definition.

Further obscuring the meaning of "oxytocin analog," non-limiting examples of oxytocin analogs is presented in the specification (p. 6, lines 10-21, and p. 10, line 11 to p. 11, line 4), which are also recited in claims 2, 7, 16, and 24. In both the specification and the claims, abbreviations are used that do not describe the compounds with adequate specificity such that one of ordinary skill in the art would know which specific compounds Applicant intended to identify. These abbreviations are not further clarified

or explained anywhere in the disclosure. Finally, every claim suffers from this defect, because the specification defines the term oxytocin to refer to "oxytocin, oxytocin analogs, and combinations thereof (p. 9, lines 4-5).

As stated *supra*, the MPEP states that written description for a genus can be achieved by disclosing a representative number of species within a broad generic group. Certainly, the claims are broad and generic, with respect to all possible compounds they encompass. While having written description for oxytocin itself, the specification does not provide sufficient descriptive support for the ambiguous and myriad compounds embraced by the claims.

The written description requirement of 35 U.S.C. 112 requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, the specification fails to provide adequate written description for the claimed genus and does not reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the full scope of the claimed invention.

Claim Rejections - 35 USC § 112 Second Paragraph

Indefiniteness

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 18 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "10 μg/ml" is a relative term which renders the claims indefinite because it is recited as a "therapeutically effective amount." Units given in μg per ml denote a *concentration* of a solution of undefined volume, not a *dose*, which is given in absolute terms (for example, μg per kg of body weight of the patient). The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 5, 6, 12, 15, 19, 23, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Knauf (DE 4429880, published 3/31/1994).

Knauf teaches methods of treating austistic children and adults by administering a pharmaceutical composition containing oxytocin, alone or in combination with vasopressin or endorphins (p. 2, lines 53-59; p. 3, line 59 to p. 4, line 8). The autistic patient population of Knauf reasonably encompasses not only individuals "demonstrating behavioral characteristics associated with autism" as recited in claims 1, 5, 6, 12, but also individuals "with a disorder including repetitive behaviors, social deficits and cognitive deficits" as recited in claims 15, 19, 23, and 28. The administration of oxytocin alone reads on claims 1, 5, 15, and 19. The administration of oxytocin with endorphins, which have an opiate effect (p. 2, line 37) and therefore can be considered psychopharmacologic agents, reads on claims 6, 12, 23, and 28.

12. Claims 1, 2, 4-9, 11, 12, 15-19, and 23-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Quay (US Pat 6,894,026, filed 10/3/2000).

Quay teaches methods of administering a therapeutically effective amount of the oxytocin analog carbetocin, and/or other long-acting oxytocin analogs, either alone or coordinately with an antidepressant such as a selective serotonin receptor antagonist (SSRI), to prevent, treat, or alleviate the symptoms of autism (col. 5, lines 39-49 and col. 6, lines 24-38). This reads on claims 2 and 16, which recite the oxytocin analog carbetocin; claims 7 and 24, which recite the co-administration of psychopharmacologic agents in addition to the oxytocin analog carbetocin; claims 8 and 25, which recite an antidepressant as the psychopharmacologic agent; claims 9 and 26, which recite a psychopharmacologic agent affecting the serotonergic system.

The claims are interpreted in light of the specification, which defines the term "oxytocin" to refer to oxytocin, oxytocin analogs, and combinations thereof (p. 9, lines 4-10). Therefore, the teachings of Quay also read on claims reciting oxytocin, namely claims 1, 5, 6, and 12; and since the autistic patient population of Quay reasonably encompasses individuals "with a disorder including repetitive behaviors, social deficits and cognitive deficits," claims 15, 19, 23, and 28 are also anticipated.

Quay also teaches the administration of the oxytocin analog carbetocin in doses ranging from 0.1 μg to 5 mg per administration (col. 13, lines 58-61), which can be multiple times daily (col. 14, line 20), and could, therefore, occur hourly. Claims 4 and 11 recite the administration of oxytocin in an amount from 0.1 to 7 units per hour. If this is interpreted as USP units, one USP unit is defined in the specification as approximately 2 μg (p. 22, lines 13-14), so that the amounts recited in claims 4 and 11 are equal to 0.2 to 14 μg per hour, a range which is anticipated by Quay. This range also reads on the amount recited in claims 18 and 27 (10 μg/ml).

Finally, Quay teaches the methods and compositions described above to treat obsessive-compulsive behaviors, which, like autism, is associated with repetitive behaviors (Example V, col. 28, lines 13-33), which reads on claim 17.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knauf (DE 4429880, published 3/31/1994) in view of Quay (US Pat 6,894,026, filed 10/3/2000).

As discussed above, Knauf teaches the administration of oxytocin to autistic adults and children, a patient population which reasonably encompasses individuals "demonstrating behavioral characteristics associated with autism" as recited in claim 13, as well as individuals "with a disorder including repetitive behaviors, social deficits and cognitive deficits" as recited in claim 14.

However, Knauf does not teach the administration of oxytocin in any specific amounts or by any particular route.

As discussed above, Quay teaches the administration of the oxytocin analog carbetocin in doses ranging from 0.1 μg to 5 mg per administration; and that, because oxytocin has a relatively short half-life of only about four to ten minutes in the human system, it must generally be administered by continuous intravenous (IV) infusion (col. 3, lines 53-56). Therefore, in the absence of evidence of the criticality of the doses and timing, the hourly dosing regimen recited in claims 13 and 14 would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.. As recognized by MPEP 2144.05:

> Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

> by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

15. Claims 21 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knauf (DE 4429880, published 3/31/1994), in view of Begley et al. (Newsweek, 127(20), page 70, May 13, 1996).

Knauf teaches the administration of an oxytocin composition, alone or in combination with another psychopharmacologic agent, as a method of treating individuals with disorders such as autism, which is characterized by repetitive behaviors and social and cognitive deficit; as well as disorders such as bed-wetting, which can be regarded as a repetitive behavior, and sexual killers, who can be considered to have social and possibly cognitive deficits. However, Knauf does not teach the administration of an oxytocin composition, alone or in combination with another psychopharmacologic agent, to treat Social Anxiety Disorder.

Begley et al. report that "[t]he social phobia of autism may be linked to the brain chemical oxytocin. This molecule, best known for inducing labor and lactation, also promotes maternal and other bonds and so has come to be known as the sociability molecule. When Hollander, this is in a quote from the Begley reference, administered oxytocin to five autistic patients, it made them four times more talkative and, according to the patients, twice as 'happy.'" The symptoms and boundaries of Social Anxiety Disorder are blurry, and not elaborated upon in the specification, but results such as these would reasonably be expected to be a desired outcome for individuals having social deficits or phobias.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to be motivated to use oxytocin to treat symptoms of autism, as taught by Knauf and Begley et al., more specifically to alleviate the symptoms of Social Anxiety Disorder, with a reasonable expectation of success, since the clear-cut, positive results reported by Begley et al. in the treatment of autistic individuals would have suggested the use of oxytocin for such conditions.

Conclusion

16. Claims 1, 2, 4-9, 11-19, 21, 23-28, and 30 are rejected.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon - Thu, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SEC

/Patrick J. Nolan/
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